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Heelbo, Inc.
Checkmate Ankle Restraint System

Safety and Effectiveness Summary

1. Submitter's name, Address and Contact Person

Submitter

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Contact Person

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Date Summary Prepared - July 25, 1996

2. Name of Device:

Checkmate Ankle Restraint System

3. Name of Predicate Device(s)

Checkmate Ankle Restraint System

4. Description of Device

The Checkmate Ankle Restraint System is designed for situations requiring patient control. The Checkmate System is a restraint system that secures the patient's ankles in a fixed position. It consists of two individual quilted ankle restraints that are permanently attached at a specific distance apart from each other to a long security strap. The security strap is constructed from a woven polypropylene fabric that is 4 inches wide and 33 inches long. The webbed straps attached to both ends of the security strap secure the ankle restraint system to a bed or gurney. The individual ankle restraints are made of a soft polyester and polyurethane foam laminate that forms a cuff that closes around the patient's ankle. The ankle restraint is held securely closed with Velcro® (hook and loop) and a Double D-Ring closure with strap.

5. Statement of Intended Use

The Checkmate Ankle Restraint System is intended to be used in situations requiring patient control while the patient is lying on a bed or gurney. The Checkmate Ankle Restraint System is intended to secure the patient's ankles by keeping them in a fixed position.

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6. Statement of Technological Characteristics of the Device

The Checkmate Ankle Restraint System is designed for situations requiring patient control. The Checkmate System is a restraint system that secures the patient's ankles in a fixed position. It consists of two individual quilted ankle restraints that are permanently attached at a specific distance apart from each other to a long security strap. The security strap is constructed from a woven polypropylene fabric that is 4 inches wide and 33 inches long. The webbed straps attached to both ends of the security strap secure the ankle restraint system to a bed or gurney. The individual ankle restraints are made of a soft polyester and polyurethane foam laminate that forms a cuff that closes around the patient's ankle. The ankle restraint is held securely closed with Velcro® (hook and loop) and a Double D-Ring closure with strap.

The subject devices are identical in intended use, design, materials, manufacturing process, physical and mechanical specifications and issues of safety and effectiveness to the devices prior to the submission of this notification. The only difference is that the product labeling has been revised to comply with the Agency's labeling requirements set forth in the draft "Guidance on the Content of Premarket Notification [501(k)] Submissions for Protective Restraints" dated December 1995.

7. Biocompatibility Assessment

The subject devices are identical in component materials to the predicate devices. The suppliers of the materials use in the fabrication of these devices have stated that there is a history of safe use of their materials in the clothing and garment industry. In addition, Heelbo, Inc., is not aware of any reports or complaints of skin irritation associated with these materials.

8. Conclusion

Based upon the information presented above it is concluded that the proposed Checkmate Ankle Restraint System is safe and effective for its intended use and is substantially equivalent to the predicate device.